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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	PAPER NUMBER
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/087,599	CONSTANTZ ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-54* is/are pending in the application.

4a) Of the above claim(s) *35-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23, 25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 06/18/09 have been entered.

Claims 1-23, 25-34 are present for examination.

Claims 35-54 are withdrawn.

Claim 24 is cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant only discloses that "the porous element is configured to provide for a flow rate that typically ranges from about 0.1 ml/hr to about 10l/hr, usually from about 600 ml/hr to about 3l/hr", see para [27, 42]. According to Specification in para [42], it states that: the fluid delivery element is configured to provide for the desired flow rate of fluid to the porous applicator. As such, this element is configured to provide for a flow rate that typically ranges from about 0.1 ml/hr to about 100 l/hr, usually from about 600 ml/hr to about 3l/hr. In other words, the fluid delivery element (not the porous region) is configured to provide for a flow rate that typically ranges from about 0.1 ml/hr to about 100 l/hr, usually from about 600 ml/hr to about 3l/hr. Furthermore, the fluid delivery element is silent about two ways fluid flow with the range about 600 ml/hr to about 3l/hr.

Nowhere in the specification discloses the feature "the porous region being configured, for two ways fluid flow of between 600 ml/h and 3 l/h", as recited in claims 1, 12, 21 and 31.

For examining purpose, Examiner interprets as: the fluid delivery element is configured to provide for flow rate that typically ranges between 600 ml/hr to about 3 l/hr.

Claims 2-11, 13-20, 22-30, 32-34 are also rejected since they depend on claims 1, 12, 21, 31.

In claim 23, nowhere in the Specification discloses that an aortic valve ventricular side occlusion element. Does Applicant mean that the aortic valve ventricular side occlusion element as a valve occluder 29?

For examining purpose, Examiner interprets that the aortic valve ventricular side occlusion element is as the ventricular side valve occluder 29. Beside that, the ventricular side valve occluder 29 may also be a balloon or other occlusive device, as Applicant admitted in lines 2-5, para [53], page 16 of Specification).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23, 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 5,842,971).

As best as understood, regarding claims 1-6, 9-11, Yoon discloses, in Figs. 1-2 or 13, a device for localized contact of a fluid to a target physiological site, said device comprising:

(a) a fluid delivery element 10 having a proximal and distal end;

(b) a an unobstructed, compliant porous region 18, 20 at said distal end of said fluid delivery element through which fluid must flow to contact said a target physiological site, the porous region being formed from a compliant material and the fluid tube 42 or 36A (can be aspiration/and or irrigation lines, col. 9, lines 25-35) connected with inlet lumen 44 to make flush juxtaposition with the target physiological site. As noted that, the port 44 is aspiration and/or irrigation port (col. 9, lines 25-35).

(c) an aspiration element in fluid communication with the unobstructed, compliant porous region.

Yoon discloses that the port 44 communicates with a valve 46, such as stop cock, for controlling fluid flow there through. Therefore, the fluid delivery element line 44 through 36A can be flowed slow or fast by the controlling of the stop cock valve 46.

It has been held that the recitation that a fluid delivery element is "configured to/capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Yoon does not specially mention the amount of flow rate between 600 ml/h and 3 l/h; beside that, the limitation "fluid delivery element" above is a functional limitation.

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide a fluid delivery element with flow rate between 600 ml/ to 3l/hr, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 7-8, 15-16, 29-30, Yoon discloses the invention substantially as claimed. Robertson does not disclose the device includes an external energy application element. However, Applicant admitted on page 13 of Specification that it is well-known in the art to provide the means of applying external energy for delivering ultrasound to physiological sites.

Regarding claims 11, 17, the device further comprises a second fluid delivery element 42 (opposite side) or 242' (Fig. 17A); 342' (Fig. 18).

Regarding claims 12-14, similarly to the rejection of claims 1-3 above, the device is normally disposed in a small size opening in a body cavity wall, therefore, one skill in the art would recognize that the device of Yoon can be used and contact a target vascular site.

Regarding claims 18-21, it has been held that the recitation that the porous fluid flow path is "adapted to/capable of/configured to…" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Regarding claim 22, the device further comprising: porous fluid flow path 20 having many different separate fluid flow paths.

Regarding claims 23-24, according to the Specification, Applicant denotes an occlusion element as balloon or other occlusive device, para [53], page 16. Similarly, the element 92 (Fig. 13), 192 (Fig. 16); 292 (Fig. 17A) are considered as an occlusion element.

Regarding claim 21, the device further comprises a cap element 54 (Fig. 2) proximal to the porous fluid flow path.

Regarding claims 28 and 32, a fluid driving element 36A-D (Figs. 1-13) or 48 (Figs. 1-13); 240 (Fig. 17A) for driving fluid out of the porous fluid flow path.

Regarding claim 31, similar to the rejection of claims 1, 21, 26-26 above.

Claims 1-6, 9-14, 17-20, 21, 23, 25-26 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson (US 4.344.434).

As best as understood, regarding claims 1-6, 9-10, 12-14, Robertson discloses a device for localized contact of a fluid to a target physiological site, said device comprising:

(a) a fluid delivery element 34 having a proximal and distal end;

(b) a an unobstructed, compliant porous region 40 at said distal end of said fluid delivery element through which fluid must flow to contact said a target physiological site, the porous region being formed from a compliant material and the fluid tube connected with inlet lumen 20/22 to make flush juxtaposition with the target physiological site; and

(c) an aspiration element (col. 8, lines 44-45). Robertson further states that the fluid control means forms a means which is adapted /configured for removing/flowing fluid from and the application of fluid to the hollowed-out central are 102.

It has been held that the recitation that a fluid delivery element is "configured to/capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Robertson does not specially mention the amount of flow rate between 600 ml/h and 3 l/h; beside that, the limitation "fluid delivery element" above is a functional limitation.

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide a fluid delivery element with flow rate between 600 ml/ to 3l/hr, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 11 and 17, the device further comprises a second fluid delivery element 36.

Regarding claims 18-20, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., "…configured to conform to a vascular structures such as a valve sinus or aortic sinus" functional limitations, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Regarding claim 21, Robertson discloses the invention substantially as claimed as discussed above. The porous fluid flow path is capable to fit inside of an aortic sinus of said aortic valve; the porous fluid flow path is capable of contacting the aortic valve.

It has been held that the recitation that porous fluid flow path is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Regarding claims 23, 25-26, 28, Robertson further discloses that a shunt element 200; a plug 100. As noted that, Applicant defines that plug is as a covering of porous material that covers the porous tip (para [0075]). Similarly, the membrane 100 is performing same function as the plug of claimed invention.

Claims 22, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson in view of von Dyck (US 6,033,390).

Robertson discloses the invention substantially as claimed. Robertson does not disclose the device comprises a separate porous fluid flow path; a cap element proximal to the porous fluid flow path.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. for each different aortic sinus of said aortic valve, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it

from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974)

Von Dyck discloses similar device with separate porous fluid flow paths 216 (Fig. 13), as noted that these fluid flow path is capable of flowing each different aortic sinus of the aortic valve; a cap element 128 proximal to the porous fluid flow path.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Robertson with a cap and separate porous fluid flow paths, as taught by von Dyck, in order to delivery drugs at different locations and the cap for protecting the device.

Response to Arguments

Applicant's arguments with respect to claims 1-23, 25-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763